IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of
Heinz-Werner Kleeman, et al.

Examiner: R. Anderson

Art Unit: 1626

Application No.: 10/749,631

Filed: December 31, 2003

Title: 3-Guanidinocarbonyl-1-heteroaryl-indole Derivatives, Preparation process, Their Use as Medicaments, and Pharmaceutical Compositions Comprising Them

Commissioner of Patents
P. O. Box 1450
Alexandria, VA 22313-1450

PETITION UNDER 37 C.F.R. § 1.144 FROM A REQUIREMENT FOR RESTRICTION

Dear Sir:

In response to a Final Office Action dated September 8, 2006 (hereinafter "the Action"), Applicants hereby petition for the review of the finality of a Restriction Requirement, dated October 25, 2005 (hereinafter "Original Restriction Requirement), and subsequent treatment of Applicants' elected subject matter. Specifically, Applicants petition for the review of the Action's objection to, and requirement to withdraw, Applicants' non-elected species. In addition, Applicants file herewith, a response to the outstanding Action.

DISCUSSION

I. Status of Claims

Claims 1-49 are pending in the present application. Claims 7-19 21-32, 34-48 have been withdrawn from consideration as being directed to non-elected subject matter, and the Action has objected to claims 1-6, 20 and 33 (to the extent these claims are directed non-elected subject matter). Claims 1,2,5,6,20, and 33 stand rejected under the judicially created doctrine of obviousness-type double patenting. To advance prosecution, Applicants concurrently file herewith, a response to the outstanding Action.

Applicants have not attached copies of Applicants' responses or Office Actions in the pending application, as both are readily available to the Patent Office for reference through internal records or by the PAIR system.

II. Election/Restriction Requirement

The Action has made final a Restriction Requirement, mailed on October 25, 2005, under 35 U.S.C. § 121, which required Applicants to elect between the following groups of claims.

Group I, claims 1-6,20, and 33, drawn to the products of the formula (I);
Group II, drawn to the methods of use for the products of the formula (I); and
Group III, drawn to a process for the preparation of the products of the formula (I).

Applicants' reply of November 22, 2005, elected Group I along with a Markush species that included, in relevant part, **Ar is 7H-pyrrolo-[2,3-d]-pyrimidine** recited by formula (1), of claim 1. The subsequent Office Action of February 26, 2006, acknowledged Applicant's election, but further objected to all species within claim 1, except for 7H-pyrrolo-[2,3-d]-pyrimidine, stating that these "non-elected" species "materially differ in structure and composition from the compounds of the elected invention" and have "recognized chemical diversity ... as seen in the U.S. classification system". Furthermore, the February Office Action (at page 3) further asserted that:

> The remaining compounds which are not within the elected invention, which are distinct from the elected invention and do not have unity with the elected compound and are therefore withdrawn my means of restriction requirement within the claims are, for example, the compounds of formula (I) wherein Ar is for a 9 to 10 membered bicyclic heteroaryl other than 7H-pyrrolo-[2,3-d]-pyrimidine, for example wherein Ar is quinoline, isoquinoline, or qunazoline." (Emphasis Added).

Therefore, the Action maintains, the elected invention for search and examination is limited to the single species within claim 1 were, in relevant part **Ar** is 7H-pyrrolo-[2,3-d]-pyrimidine. In addition, the Action required Applicants to withdraw the non-elected species by stating that, "[c]laims 1-6,20, and 33 presented drawn solely to the elected invention identified ... wherein **Ar** is 7H-pyrrolo-[2,3-d]-pyrimidine would overcome this objection." (Emphasis added). To support the aforementioned requirement, the Action cites the Commissioner's (Director's) authority to restrict inventions under 35 U.S.C. § 121.

III. Applicant's Response

(a) Applicants Traversal

As required under MPEP § 818.03(c), Applicants have consistently provided factual and legal bases under which the Original Restriction Requirement and subsequent Office Actions have misapplied established rules of practice to sustain the Restriction Requirement. Specifically, Applicants refer to responses dated November 22, 2005, and June 26, 2006, which distinctly and specifically pointed out errors in the Restriction Requirement. In addition, Applicants' later response of June 26, 2006, requested reconsideration of the Original Restriction Requirement, and therefore, Applicants statements in both responses, procedurally meet the legal requirements to effectively support traversal of the Restriction Requirement. Indeed Applicants reaffirm that election of Group I, and the accompanying species was made **with traverse**.

(b) Response

To the extent the Action requires Applicants to elect a single Markush species, at the exclusion other recited species within Group I, Applicants submit that such a requirement cannot be sustained as a matter of law, absent a showing that the claimed species are either

patentably distinct or exceed a reasonable number of species. Although 35 U.S.C. § 121 authorizes the Commissioner (Director) to substantively restrict an application claiming two or more inventions to a single invention, procedurally, § 121 does not alleviate the Examiner of demonstrating the aforementioned prerequisites. The Action must either provide reasoning to support the requirement for restriction - more than mere conclusions that the species "materially differ in structure and composition from the compounds of the elected invention"- or demonstrate that the species exceed a reasonable number causing a burden for Examination. Furthermore, an Applicant may not be required, "under the guise of § 121, to divide up the embodiments of a single Markush claim." In re Weber, 580 F. 2d 445 (C.C.P.A. 1978). The elected species and Group must be examined, and if allowable, the non-elected species must also be examined. (MPEP 803.02).

In addition, restriction requirements directed to a single claim under § 121, have been addressed, and In reWeber is instructive as authoritave case law. Specifically, the CCPA has stated:

> An applicant is given, by the statute, the right to claim his invention with the limitations he regards as necessary to circumscribe that invention, with the proviso that the application comply with the requirements of § 112.
>
> As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. ... If, however, a single claim is divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the sub-genera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

In re Weber, Soder, and Boksay, 198 USPQ 328, 331 (CCPA 1978).

In the present case, Applicants provisionally elected 7H-pyrrolo-[2,3-d]-pyrimidine, as a species for initial examination, if allowable, the non-elected species - quinoline, isoquinoline, or qunazoline - should have been examined. By contrast, the Action first required Applicants to withdraw the non-elected species from consideration, before the elected species was examined against any prior art. (MPEP 803.02). Significantly, such a requirement contradicts the above-described principles of Restriction. Controlling case law, such as, In re Weber, supports an Applicant's statutory right to claim his invention with the

limitations he regards as necessary to circumscribe that invention; with the proviso that the application complies with the requirements of § 112. In turn, requiring an Applicant to limit her claimed invention to one species or embodiment, curtails Applicants aforementioned right. At the very least, the Action has fundamentally failed to cite any prior art that compromises the patentability of the elected or non-elected species. The closest prior art mentioned, U.S. Patent No. 5,862,046 to Lang (hereinafter "Lang"), substantively fails to anticipate or render obvious the elected or non-elected species. Accordingly, in view the aforementioned procedural and substantive deficiencies, Applicants submit that Action's requirement to parse out the Markush claim between the elected and non-elected species within the claim cannot be sustained and must be withdrawn.

Applicants further point out that the Action's requirement to withdraw non-elected subject matter within the claim is also improper for another for reasons related to Unity of Invention. Specifically, Unity of Invention exists between the Markush group of species where the species share: (1) a common utility; and (2) a substantial structural feature disclosed as being essential to that utility, unity of invention is recognized.

In the present case, Applicants' elected species share a common utility, namely, their ability as substituents on the structure of formula 1 to affect cardiac arrhythmias and heart failure. Second, the elected species also share a common substantial structural feature, namely, their relation to each other as 9-10 membered bicyclic ring structures that include at least one nitrogen atom, as recited by claim 1. So, in view of the common utility and structural similarity of the non-elected species that include quinoline, isoquinoline, or qunazoline, for example, the Action's assertion to the contrary cannot be sustained. Moreover, where the Action alleges that the "non-elected" species "materially differ in structure and composition from the compounds of the elected invention", Applicants submit that such a statement, unsupported by the requisite reasoning, fails to support an election of species requirement under MPEP 803.02. Accordingly, Action's requirement to parse out the Markush claim by requiring Applicants to withdraw the non-elected species claim cannot be sustained and must be withdrawn.

(a) Final Office Action

As indicated above, Applicants have concurrently filed a response to the outstanding Action, including a Terminal Disclaimer to obviate the Action's rejection of claims 1,2,5,6,20, and 33. Applicants, therefore, (1) request withdrawal of the Action's rejection of the those claims, and (2) in view of the aforementioned procedural and substantive errors in restriction, Applicants also request withdrawal of the finality of the Action and implore allowance of the elected group of claims, including the accompanying Markush species.

IV. Conclusion

In sum, Applicants maintain (1) procedurally, the Action's requirement to withdraw non-elected subject matter within the claim is improper because it requires Applicants to parse out the non-elected species, before citing prior art against the elected species, and (2) substantively, a restriction requirement under § 121 cannot be applied to a single claim under the holding of In re Weber et al., especially where the elected species share a common utility and structural feature.

Therefore, Applicants respectfully petition the Commissioner to remove both the restriction requirement pursuant to 37 C.F.R. § 1.144, to the extent that it applies to the withdrawal of the non-elected species; and second, the finality of the outstanding Action, as the pending application is directed to allowable subject matter.

The Commissioner is hereby authorized to charge the fee required and any additional fees that may be needed to Deposit Account No. **18-1982** in the name of Aventis Pharmaceuticals Inc.

Respectfully submitted,

Robert Kajubi 12/15/06

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